2018 Current Fiscal Year Report: Dermatologic and Ophthalmic Drugs Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018

3. Committee or Subcommittee	3b. GSA Committee No.
Dermatologic and Ophthalmic Drugs Advisory Committee	108

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	10/07/2016	10/07/2018	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 394	11/28/1990	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 1 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 1

Meetings and Dates

Purpose	Start	End
The committee discussed the safety and efficacy of new drug application (NDA) 208254, for netarsudil ophthalmic solution 0.02%, submitted by Aerie Pharmaceuticals Inc., for the proposed indication to reduce elevated intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT).	10/13/2017	10/13/2017

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$1,572.00	$6,015.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$163,941.00	$162,146.00
18a(4). Personnel Pmts to Non-Member Consultants	$3,143.00	$6,562.00
18b(1). Travel and Per Diem to Non-Federal Members	$2,407.00	$6,656.00
18b(2). Travel and Per Diem to Federal Members	$798.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$5,713.00	$11,486.00

18c. Other(rents,user charges, graphics, printing, mail, etc.)	$42,188.00	$42,966.00
18d. Total	$219,762.00	$235,831.00
19. Federal Staff Support Years (FTE)	1.10	1.10

20a. How does the Committee accomplish its purpose?

The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of dermatologic and ophthalmic disorders. The committee answers questions that are designed to help the Agency's efforts in completing its review and to reach a final decisions on new drug applications.

20b. How does the Committee balance its membership?

Members are experts in clinical dermatology, dermatopathology, internal medicine, immunology, ophthalmology, and biostatistics. The committee includes one technically qualified voting member who is identified with consumer interests. The Committee may include one non-voting member who is identified with industry interests.

20c. How frequent and relevant are the Committee Meetings?

The committee met one time during FY-18. On October 13, 2017, the committee discussed the safety and efficacy of new drug application (NDA) 208254, for netarsudil ophthalmic solution 0.02%, submitted by Aerie Pharmaceuticals Inc., for the proposed indication to reduce elevated intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT). The committee agreed unanimously that the clinical trials support the efficacy of netarsudil ophthalmic solution for reducing elevated intraocular pressure inpatients with open-angle glaucoma or ocular hypertension. The majority of the committee agreed that the efficacy of netarsudil ophthalmic solution, demonstrated in the clinical trials, outweigh the safety risks identified for the drug product.Agency Action: The Agency is still reviewing all recommendations that were made at the meeting. It is expected that the committee will meet two times during FY-19.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

Members of the committee are drawn from academia, research and/or clinical practice. Their advice and input lends credibility to FDA regulatory decisions. The alternate means of obtaining this advice would involve the recruitment of large numbers of scientists on a full time basis at maximum rates of compensation.

20e. Why is it necessary to close and/or partially closed committee meetings?

The committee held no closed meetings during FY-18.

21. Remarks

No reports are required for this committee

Designated Federal Officer

LaToya A. Bonner DFO

Committee Members	Start	End	Occupation	Member Designation
Bigby, Michael	03/30/2016	08/31/2019	Associate Professor of Dermatology/Beth Israel Deaconess Medical Center	Special Government Employee (SGE) Member
Capozza, Korey	09/19/2016	08/31/2020	CONSUMER REPRESENTATIVE, Director, Global Parents for Eczema Research	Special Government Employee (SGE) Member
Chodosh, James	09/01/2017	08/31/2021	DG Cogan Professor of Ophthalmology, Harvard Medical School	Special Government Employee (SGE) Member
Emerson, Geoffrey	04/16/2015	08/31/2018	Physician, Retina Center of Minnesota	Special Government Employee (SGE) Member
Gicheru, Sydney	10/28/2016	08/31/2020	President, Ophthalmologist LaserCare Eye Center, P.A, Irving, Texas	Special Government Employee (SGE) Member
Hartnett, Mary	10/28/2016	08/31/2020	Director of Pediatric Retina, Ophthalmologist	Special Government Employee (SGE) Member
Katz, Kenneth	03/30/2016	08/31/2022	Dermatologist, Kaiser Permanente	Special Government Employee (SGE) Member
Murray, Timothy	09/01/2018	10/31/2022	Director, Miami Ocular Oncology and Retina	Special Government Employee (SGE) Member
Siegfried, Elaine	09/01/2017	08/31/2021	Professor, Pediatrics and Dermatology	Special Government Employee (SGE) Member
Sultan, Marla	03/31/2016	10/31/2019	Global Clinical Lead, Clinical Development, Pfizer, Inc.	Representative Member
Weng, Christina	09/01/2018	08/31/2022	Assistant Professor of Ophthalmology, Baylor College of Medicine	Special Government Employee (SGE) Member
Yoo, David	04/16/2015	08/31/2018	Residency Program Director - Ophthalmology, Loyola University Medical Center	Regular Government Employee (RGE) Member

Number of Committee Members Listed: 12

Narrative Description

FDA’s strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Dermatologic and Ophthalmic Drugs Advisory Committee supports FDA's strategic priorities by reviewing and evaluating available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disorders and makes appropriate recommendations to the Commissioner of Food and Drugs. This supports the development of safe and effective new medical technologies, and advances

the status of the Agency as a science-based and science-led regulatory agency, providing global leadership in the protection of public health.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

N/A

What are the cost savings associated with this committee?

	Checked if Applies
None	
Unable to Determine	✓
Under $100,000	
$100,000 - $500,000	
$500,001 - $1,000,000	
$1,000,001 - $5,000,000	
$5,000,001 - $10,000,000	
Over $10,000,000	
Cost Savings Other	

Cost Savings Comments

The utilization of the Dermatologic and Ophthalmic Drugs Advisory Committee enabled the Agency to obtain required and frequently scarce professional services from the medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the Committee resulted in advice for the improvement of the public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee

for the life of the committee?
28

Number of Recommendations Comments
The Committee made 28 recommendations from FY-03 through FY-18. See question 20a of the annual report for specific accomplishments.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
79%

% of Recommendations Fully Implemented Comments
The function of an advisory Committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
7%

% of Recommendations Partially Implemented Comments
The function of an advisory Committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?
Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments
It usually does. Product approval issues are first released to the sponsor. When appropriate, information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

Checked if Applies

Reorganized Priorities	✓
Reallocated resources	
Issued new regulation	✓
Proposed legislation	
Approved grants or other payments	
Other	✓

Action Comments

FDA approves or chooses not to approve an investigational new medical product.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

N/A

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	✓
Online Agency Web Site	✓
Online Committee Web Site	✓
Online GSA FACA Web Site	✓
Publications	✓
Other	

Access Comments

N/A